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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,715	07/20/2001	Brian J. Cox	18455.11	1492

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STRADLING YOCCA CARLSON & RAUTH
SUITE 1600
660 NEWPORT CENTER DRIVE
P.O. BOX 7680
NEWPORT BEACH, CA 92660

EXAMINER

PANTUCK, BRADFORD C

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,715

Applicant(s)

COX, BRIAN J.

Examiner

Bradford C Pantuck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 1, 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-47 and 51-86 is/are pending in the application.
- 4a) Of the above claim(s) 59, 70-75, 78-80, 86 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 69 is/are allowed.
- 6) ☒ Claim(s) 44-47, 51-56, 60-68, 76, 77, and 81-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9-23-04, 10-14-04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: IDS 11-05-2004.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 44-47, 51-56, 60-62, 64-68, 76, 77, and 81-84 are rejected under 35

U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,613,074 B1 to Mitelberg et al. Regarding Claims 44, 46, 51, 52, 67, and 81, Mitelberg discloses an apparatus for treating vascular aneurysms including six fenestrations, i.e. windows or openings, as labeled in Attachment A. The body of the stent is cylindrical and blood flows through the internal lumen. A reactive material (hydrogel) [column 5, lines 32-33] is applied to fenestrations 2-4 (“not all”), as shown in Figure 6. Hydrogels react in the presence of liquids, in this case blood. Hydrogel (38) “is intended to significantly reduce...the flow into the aneurysm” [column 5, lines 26-29]. In other words, applying a hydrogel to the fenestrations increases the resistance of blood flow through the fenestrations (compared to naked frame shown in Fig. 5), but *still allows some blood to flow into the aneurysm*. Mitelberg’s stent is radially expandable to be the size of the interior lumen of the blood vessel [Column 2, lines 38-39].

2. Regarding Claim 45, the reactive material can be an expandable polymer, such as silicone, polyether, polyurethane, etc... [Column 5, lines 31-34].

3. Regarding Claims 47 and 56, because Mitelberg's reactive material (38) is a hydrogel, just like the Applicant's, it will react in the same ways to the blood (including the pH of the blood), and other internal fluids and proteins of the vasculature.
4. Regarding Claims 53 and 54 the reactive material can be considered to be integrally formed with the stent.
5. Regarding Claims 55 and 56, because Mitelberg's reactive material (38) is a hydrogel, just like the Applicant's, it will have a reacted volume V' and a non-reacted volume V . Hydrogels, by definition, expand upon exposure to liquids.
6. Regarding Claims 60, 61, and 84, Mitelberg's stent is delivered by a catheter [Column 3, lines 52-65; Figures 2, 3, and 4].
7. Regarding Claim 62, Mitelberg discloses an attachment device (36), which fits snugly inside the vessel, attaching the stent (30) to the inner lumen of the blood vessel.
8. Regarding Claim 64, Mitelberg's stent (12/30) [Figures 5/6] is made out of titanium [Column 4, lines 60-67].
9. Regarding Claim 65, Mitelberg's stent comprises radio-opaque materials [Column 2, lines 56-58].
10. Regarding Claim 66, Mitelberg's support member can be made out of all of the materials disclosed as the applicant's support member, and will therefore have the same properties as the Applicant's. For that reason, although not specifically

disclosed as “echo-genic,” Mitelberg’s support member will have internal echoes, just like the Applicant’s.

11. Regarding Claims 68 and 76, Mitelberg discloses a helical stent, having a wire (36/34) [Fig. 6] that forms a three-dimensional curve that lies on a cylinder, so that its angle to a plane perpendicular to the axis is constant. At least parts of the wire (36/34) form parts of a spiral.
12. Regarding Claim 77, Mitelberg discloses a reticulated stent (forming a network with separate holes) in which reactive material (38) is applied to not all of the support members [see Fig. 6].
13. Regarding Claims 82 and 83, Mitelberg’s reactive material (hydrogel) *will* obtain a reacted volume V’ in the presence of a physiological pH of about 7.4. *The normal pH of blood is between 7.35 and 7.45* [MedicineNet.com article], and because Mitelberg’s invention is meant to be applied to the inside of blood vessels, the reaction (swelling) will occur at a pH of about 7.4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.

Patent No. 6,613,074 B1 to Mitelberg et al. Mitelberg discloses an attachment device

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(36), but fails to disclose a barb, hook, needle, spur, or adhesive means to attach the stent to the blood vessel. However, such means are extremely well known in the art of stents and are often placed at the ends of the stent to make sure that the stent stays in position.

15. Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,613,074 B1 to Mitelberg et al. in view of Publication No. 2002 to Marotta. Mitelberg discloses a self-expanding prosthesis/stent (12) [see progression from Fig. 3 to Fig. 4; Column 2, lines 36-40] only. Marotta teaches that it is well known to use either self-expanding materials (shape memory, etc...) or balloons to expand prostheses once they have been delivered to the surgical site {para. [0038]}. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver Mitelberg's stent to the surgical site instead of having it be self expanding, because these two methods are well-known *alternate and equivalent* methods of delivery.

Allowable Subject Matter

16. Claim 69 is allowed.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,596,296 to Nelson et al. (weaving hydrogel fibers)

U.S. Patent No. 6,093,199 to Brown et al. (hydrogel aneurysm embolizer)

Response to Arguments

18. Applicant's arguments, see "REMARKS", filed June 1, 2004, with respect to the rejection(s) of claim(s) 44-58, 60-69, 76, 77, 81-85 under Fogerty have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of U.S. Patent No. 6,613,074 B1 to Mitelberg et al.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
BCP

November 8, 2004


ANH TUAN T. NGUYEN
PRIMARY EXAMINER

11/11/04

